

# Exhibit 1

## CONFIDENTIAL DOCUMENT

These pages have been removed because they contain confidential information subject to the Protective Order.

## EXHIBIT 2

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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LG.PHILIPS LCD CO., LTD.,

Plaintiff,

v.

TATUNG COMPANY; TATUNG  
COMPANY OF AMERICA, INC.;  
CHUNGHWA PICTURE TUBES, LTD.;  
AND VIEWSONIC CORPORATION,

Defendants.

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Civil Action No. 05-292 (JJF)

**JOINT PROPOSED JURY INSTRUCTIONS**

July 19, 2006

3.9.2 DEFENDANTS' PROPOSED INSTRUCTION ON "SITUATIONS WHERE RESORT TO DOCTRINE OF EQUIVALENTS IS NOT PERMITTED"

There are two situations wherein resort to the doctrine of equivalents to find infringement is not permitted. First, resort to the doctrine of equivalents to find infringement is not permitted if you find that the defendant is merely practicing what was in the prior art prior to the patented invention or that which would have been obvious in light of what was in the prior art. This is because a patent owner should not obtain, under the doctrine of equivalents, coverage which he could not have lawfully obtained from the Patent Office. Accordingly, to find infringement under the doctrine of equivalents you must find that the patent owner has proven that he could have obtained from the Patent Office a hypothetical patent claim, similar to claim 8, but broad enough to literally cover the method used to manufacture the accused product. Second, resort to the doctrine of equivalents to find infringement is not permitted if you find that the patent owner is trying to recapture that which he gave up in the Patent Office to distinguish the invention from what was in the public domain prior to his invention. In other words, if the inventor, when he was in the process of obtaining his patent, limited it in some way in order to argue that it was different from what was in the public domain, then he is not now free to assert a broader view of his invention by broadening the claims through the doctrine of equivalents in an effort to recapture that which he surrendered.

Source

Uniform Jury Instructions for Patent Cases In The United States District Court For The District Of Delaware (1993).

# EXHIBIT 3

# Manual of PATENT EXAMINING PROCEDURE

Original Fifth Edition, August 1983  
Latest Revision July 1989



U.S. DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Rev. 12, July 1989

Revision 12, July 1989

U.S. DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
Washington, D.C. 20231

MANUAL OF PATENT EXAMINING PROCEDURE  
Fifth Edition

Instructions Regarding Revision No. 12

This revision consists of replacement pages for the title page in the front of the Manual, the Table of Contents (page (v)), individual replacement pages 200-3 and 200-4; 500-17, 500-18, 500-19, 500-20; entire Chapter 2200 and appendix L patent laws.

Additions to the text of the Manual are indicated by arrows (><) inserted in the text. Deletions are indicated by a single asterisk (\*) where a single word was deleted and by two asterisks (\*\*) where more than one word was deleted. The use of three or five asterisks in the body of the laws and rules indicates a portion of the law or rule which was not reproduced.

Louis O. Maassel, Editor  
Manual of Patent Examining Procedure

Revision 12, July 1989



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The cost for each 30 pages or a fraction thereof is \$10.00 (See 37 CFR 1.13(a) and 1.19(a)(3)).

Charges may be made to Deposit Accounts if the requester is an account holder in good standing at the time the request is received. Checks or money orders should be payable to the Commissioner of Patents and Trademarks. Requests must identify the specific pages required and the number of copies of each page.

Employees of the Patent and Trademark Office should direct their requests for the Manual, replacement pages, notices, and revisions to the Patent Academy.

First Edition, November 1949  
Second Edition, November 1953  
Third Edition, November 1961  
Fourth Edition, June 1979  
Fifth Edition, August 1983

Revision 1, October 1985  
Revision 2, December 1985  
Revision 3, May 1986  
Revision 4, October 1986  
Revision 5, July 1987  
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Revision 7, December, 1987  
Revision 8, May 1988  
Revision 9, September 1988  
Revision 10, January 1989  
Revision 11, April 1989  
Revision 12, July 1989

## PARTS, FORM AND CONTENT OF APPLICATION

608.01(p)

**¶ 6.18 Series of Singular Dependent Claims**

A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See § 608.01(n) MPEP.

The numbering of dependent claims and the numbers of preceding claims referred to in dependent claims should be carefully checked when claims are renumbered upon allowance.

## REJECTION AND OBJECTION

If the base claim has been cancelled, a claim which is directly or indirectly dependent thereon should be rejected as incomplete. If the base claim is rejected, the dependent claim should be *objected to* rather than rejected, if it is otherwise allowable.

Form Paragraph 7.43 can be used to state the objection.

**¶ 7.43 Objection to Claims, Allowable Subject Matter**

Claim [1] objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**608.01(o) Basis for Claim Terminology in Description [R-8]**

The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import, and in mechanical cases it should be identified in the descriptive portion of the specification by reference to the drawing, designating the part or parts therein to which the term applies. A term used in the claims may be given a special meaning in the description. No term may be given a meaning repugnant to the usual meaning of the term.

Usually the terminology of the original claims follows the nomenclature of the specification, but sometimes in amending the claims or in adding new claims, new terms are introduced that do not appear in the specification. The use of a confusing variety of terms for the same thing should not be permitted.

New claims and amendments to the claims already in the case should be scrutinized not only for new matter but also for new terminology. While an applicant is not limited to the nomenclature used in the application as filed, yet whenever by amendment of his claims, he or she departs therefrom, he or she should make appropriate amendment of the specification so as to have therein clear support or antecedent basis for the new terms appearing in the claims. This is necessary in order to insure certainty in construing the claims in the light of the specification. *Ex parte Kotler* 1901 C.D. 62; 95 O.G. 2684. See 37 CFR 1.75, >MPEP< §§ 608.01(i) and 1302.01.

The specification should be objected to if it does not provide proper antecedent basis for the claims by using Form Paragraph 7.44.

**¶ 7.44 Claimed Subject Matter not in Specification**

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP 608.01(o). Correction of the following is required: [1]

**608.01(p) Completeness [R-8]**

Newly filed applications obviously failing to disclose an invention with the clarity required are discussed in >MPEP< § 702.01.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date, *In re Glass*, 181 USPQ 31; 492 F.2d 1228 (CCPA 1974).

While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. Markush claims must be provided with support in the disclosure for each member of the Markush group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula.

A complete disclosure should include a statement of utility. This usually presents no problem in mechanical cases. In chemical cases, varying degrees of specificity are required.

A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound or composition. Incomplete teachings may not be completed by reference to subsequently filed applications.

**A. GUIDELINES FOR CONSIDERING DISCLOSURES OF UTILITY IN DRUG CASES****General**

These guidelines are set down to provide uniform handling of applications disclosing drug or pharmaceutical utility. They are intended to guide patent examiners and patent applicants as to criteria for utility statements. They deal with fundamental questions and are subject to revision and amendment if future case law indicates this to be necessary.

The following two basic principles shall be followed in considering matters relating to the adequacy of disclosure of utility in drug cases:

- (1) The same basic principles of patent law which apply in the field of chemical arts shall be applicable to drugs, and
- (2) The Patent and Trademark Office shall confine its examination of disclosure of utility to the application of patent law principles, recognizing that other agencies of the Government have been assigned the responsibility of assuring conformance to the standards established by statute for the advertisement,



608.01(p)

## MANUAL OF PATENT EXAMINING PROCEDURE

use, sale or distribution of drugs. *In re Krimmel*, 48 CCPA 1116, 292 F.2d 948, 130 USPQ 215 (1961); *In re Hartop et al.*, 50 CCPA 780, 311 F.2d 249, 135 USPQ 419 (1962).

A drug is defined by 21 U.S.C. 321(g)

The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (C) articles intended for use as a component of any articles specified in clause (A), (B) or (C); but does not include devices or their components, parts, or accessories.

In addition, compositions adapted to be applied to or used by human beings, e.g., cosmetics, dentifrices, mouthwashes, etc., may be treated in the same manner as drugs subject to the conditions stated.

Any proof of a stated utility or safety required pursuant to these guidelines may be incorporated in the application as filed, or may be subsequently submitted by affidavit if and when required. The Patent and Trademark Office, in reaching its own independent decisions on questions of utility and how to use under 35 U.S.C. 101 and 112, \*\*may\*\* avail itself of assistance and information from the Secretary of Health and Human Services as authorized by 21 U.S.C. 372(b), when necessary.

In accordance with the basic principles set forth above, the following procedures shall be followed in examining patent applications in the drug field with regard to disclosures relating to utility.

## 35 U.S.C. 101

Utility must be definite and in currently available form; (*Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689) not merely for further investigation or research but commercial availability is not necessary. Mere assertions such as "therapeutic agents," (*In re Lorenz et al.*, 49 CCPA 1227, 305 F.2d 875, 134 USPQ 312; cf. *Ex parte Brockmann et al.*, 127 USPQ 57) "for pharmaceutical purposes," (*In re Diedrich*, 50 CCPA 1355, 318 F.2d 946, 138 USPQ 128) "biological activity," (*In re Kirk et al.*, 54 CCPA 1119, 153 USPQ 48; *Ex parte Lanham*, 135 USPQ 106) "intermediate," (*In re Joly et al.*, 54 CCPA 1159, 153 USPQ 45; *In re Kirk et al.*, 54 CCPA 1119, 153 USPQ 48) and for making further unspecified preparations are regarded as insufficient.

If the asserted utility of a compound is believable on its face to persons skilled in the art in view of the contemporary knowledge in the art, then the burden is upon the examiner to give adequate support for rejections for lack of utility under this section (*In re Gazave*, 54 CCPA 1524, 154 USPQ 92). On the other hand, incredible statements (*In re Citron*, 51 CCPA 852, 325 F.2d 248, 139 USPQ 516; *In re Oberweiger*, 28 CCPA 749, 115 F.2d 826, 47 USPQ 455; *Ex parte Moore et al.*, 128 USPQ

8) or statements deemed unlikely to be correct by one skilled in the art (*In re Ruskin*, 53 CCPA 872, 354 F.2d 395, 148 USPQ 221; *In re Pottier*, 54 CCPA 1293, 153 USPQ 407; *In re Novak et al.*, 49 CCPA 1283, 306 F.2d 924, 134 USPQ 335. See also, *In re Irons*, 52 CCPA 938, 340 F.2d 974, 144 USPQ 351>; *Ex Parte Busse*, 1 USPQ 2d 1908<) in view of the contemporary knowledge in the art will require adequate proof on the part of applicants for patents.

Proof of utility under this section may be established by clinical or *in vivo* or *in vitro* data, or combinations of these, which would be convincing to those skilled in the art (*In re Irons*, 52 CCPA 938, 340 F.2d 924, 144 USPQ 351; *Ex parte Paschall*, 88 USPQ 131; *Ex parte Pennell et al.*, 99 USPQ 56; *Ex parte Ferguson*, 117 USPQ 229; *Ex parte Timmis*, 123 USPQ 581>; *Ex Parte Krepelka*, 231 USPQ 746 (PO Bd. Pa. App. & Inter. 1986), *Ex Parte Chwang*, 231 USPQ 751 (PO Bd. Pat. App. & Inter. 1986)<). More particularly, if the utility relied on is directed solely to the treatment of humans, evidence of utility, if required, must generally be clinical evidence, (*Ex parte Timmis*, 123 USPQ 581) although animal tests may be adequate where the art would accept these as appropriately correlated with human utility (*In re Hartop et al.*, 50 CCPA 780, 311 F.2d 249, 135 USPQ 419; *Ex parte Murphy*, 134 USPQ 134) >or where animal tests are coupled with other evidence, including clinical evidence and a structural similarity to compounds marketed commercially for the same indicated uses, (*In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980))<. If there is no assertion of human utility, (*Blicke v. Treves*, 44 CCPA 753, 241 F.2d 718, 112 USPQ 472; *In re Krimmel*, 48 CCPA 1116, 292 F.2d 948, 130 USPQ 215; *In re Dodson*, 48 CCPA 1125, 292 F.2d 943, 130 USPQ 224; *In re Hutchings*, 52 CCPA 1141, 342 F.2d 80, 144 USPQ 637) or if there is an assertion of animal utility, (*In re Bergel et al.*, 48 CCPA 1102, 292 F.2d 955, 130 USPQ 206; *Ex parte Melvin*, 155 USPQ 47) operativeness for use on standard test animals is adequate for patent purposes.

>The Court in *Nelson v. Bowley*, 626 F.2d 853, 206 USPQ 881 (1980) stated that knowledge of pharmacological activity of any compound is obviously beneficial to the public and concluded that adequate proof of any such utility constitutes a showing of practical utility. Where the disclosed *in vitro* utility is supplemented by the similar *in vitro* and *in vivo* pharmacological activity of structurally similar compounds, the *in vitro* utility is sufficient to comply with the practical utility requirement of 35 U.S.C. 101. *Cross v. Iizuka*, 224 USPQ 739 (Fed. Cir. 1985)<.

Exceptions exist with respect to the general rule relating to the treatment of humans. For example, compositions whose properties are generally predictable from a knowledge of their components, such as laxatives, antacids and certain topical preparations, require little or no clinical proof (*Ex parte Harrison et al.*, 129 USPQ 172; *Ex parte Lewin*, 140 USPQ 70).

Although absolute safety is not necessary to meet the utility requirement under this section, a drug which is not sufficiently safe under the conditions of use for which it is said to be effective will not satisfy the utility requirement (*In re Hartop et al.*, 50 CCPA 780, 311 F.2d 249, 135 USPQ 419; *In re Anthony*, 162 USPQ 594 (CCPA 1969); *In re Watson*, 186 USPQ 11

## PARTS, FORM AND CONTENT OF APPLICATION

608.01(p)

(CCPA 1975)). Proof of safety shall be required only in those cases where adequate reasons can be advanced by the examiner for believing that the drug is unsafe, and shall be accepted if it establishes a reasonable probability of safety.

## 35 U.S.C. 112

A mere statement of utility for pharmacological or chemotherapeutic purposes may raise a question of compliance with >35 U.S.C.<\* 112, particularly "... as to enable any person skilled in the art to which it pertains ... to use the same." If the statement of utility contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are contemplated, >35 U.S.C.<\* 112 is satisfied (*In re Johnson*, 48 CCPA 733, 282 F.2d 370, 127 USPQ 216; *In re Hitchings et al.*, 52 CCPA 1141, 342 F.2d 80, 144 USPQ 637). If the use disclosed is of such nature that the art is unaware of successful treatments with chemically analogous compounds, a more complete statement of how to use must be supplied than if such analogy were not present (*In re Mourea et al.*, 52 CCPA 1363, 345 F.2d 595, 145 USPQ 452; *In re Schmidt et al.*, 54 CCPA 1577, 153 USPQ 640). It is not necessary to specify the dosage or method of use if it is obvious to one skilled in the art that such information could be obtained without undue experimentation.

With respect to the adequacy of disclosure that a claimed genus possesses an asserted utility representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if it would be deemed likely by one skilled in the art, in view of contemporary knowledge in the art, that the claimed genus would possess the asserted utility (*In re Oppenauer*, 31 CCPA 1248, 143 F.2d 974, 62 USPQ 297; *In re Cavallito et al.*, 48 CCPA 711, 282 F.2d 357, 127 USPQ 202; *In re Cavallito et al.*, 48 CCPA 720, 282 F.2d 363, 127 USPQ 206; *In re Schmidt*, 48 CCPA 1140, 293 F.2d 274, 130 USPQ 404; *In re Cavallito*, 49 CCPA 1335, 306 F.2d 505, 134 USPQ 370; *In re Surrey*, 54 CCPA 855, 370 F.2d 349, 151 USPQ 724; *In re Lund et al.*, 54 CCPA 1361, 153 USPQ 625>; *In re Jolles*, 628 F.2d 1322, 206 USPQ 235 (CCPA 1980)<. Proof of utility will be required for other members of the claimed genus only in those cases where adequate reasons can be advanced by the examiner for believing that the genus as a whole does not possess the asserted utility. Conversely, a sufficient number of representative examples, if disclosed in the prior art will constitute a disclosure of the genus to which they belong.

In the case of mixtures including a drug as an ingredient, or mixtures which are drugs, or methods of treating a specific condition with a drug, whether old or new, a specific example should ordinarily be set forth, which should include the organism treated. In appropriate cases, such an example may be inferred from the disclosure taken as a whole and/or the knowledge in the art (e.g., gargle).

Where the claimed compounds are capable of several different utilities and one use is adequately described in accordance with these guidelines, additional utilities will be investigated for compliance with sections 101 and 112 only if not believable on their face to those of ordinary skill in the art in view of the contemporary knowledge of the art. Failure to meet these standards may result in a requirement to cancel such additional

utilities (*Ex parte Lanhan*, 121 USPQ 223; *Ex parte Moore et al.*, 128 USPQ 8; *In re Citron*, 51 CCPA 852, 325 F.2d 248, 139 USPQ 516; *In re Gottlieb et al.*, 51 CCPA 1114, 328 F.2d 1016, 140 USPQ 665>; *In re Hozumi*, 226 USPQ 353 (Dir. Group 120, 1985)<).

## B. INCORPORATION BY REFERENCE

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. *Ex parte Schwarze*, 151 USPQ 426 (Bd. of Appeals, 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See *In re Fouché*, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Nonessential subject matter may be incorporated by reference to (1) patents or application published by the United States or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications or (3) non-patent publications, for purposes of indicating the background of the invention or illustrating the state of the art.

The referencing application must include (1) an abstract, (2) a brief summary of the invention, (3) an identification of the referenced patent or application, (4) at least one view in the drawing in those applications admitting of a drawing, and (5) one or more claims. Particular attention should be directed to specific portions of the referenced patent or application.

## Complete Disclosure Filed

If an application is filed with a complete disclosure, essential material may be cancelled by amendment and the same material substituted by reference to a patent or a pending and commonly owned allowed application in which the issue fee has been paid. The amendment must be accompanied by an affidavit or declaration executed by the applicant or his >or her< attorney or agent stating that the material cancelled from the application is the same material that has been incorporated by reference.

## Issue Fee Paid

If an application incorporates essential material by reference to a U.S. patent or a pending and commonly owned allowed U.S. application for which the issue fee has been paid, applicant will be required prior to examination to furnish the Patent and Trademark Office with a copy of the referenced material together with an affidavit or declaration executed by the applicant or his >or her< attorney or agent stating that the copy consists of the same material incorporated by reference in the referencing



## 608.01(p)

## MANUAL OF PATENT EXAMINING PROCEDURE

application. However, if a copy of a printed U.S. patent is furnished, no affidavit or declaration is required.

*Issue Fee Not Paid*

If an application incorporates essential material by reference to a pending and commonly owned application other than one in issue with the fee paid, applicant will be required prior to examination to amend the disclosure of the referencing application to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant or his >or her< attorney or agent stating the the amendatory material consists of the *same* material incorporated by reference in the referencing application.

*Improper Incorporation*

The filing date of any application wherein essential material is improperly incorporated by reference to a foreign application or patent or to a publication will not be affected because of the presence of such reference. In such a case, the applicant will be required to amend the disclosure to include the material incorporated by reference.\*\*

¶ 6.19 *Incorporation by Reference, Foreign Patent or Application*

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F. 2d 569, 179 USPQ 157; *In re Hawkins*, 486 F. 2d 579, 179 USPQ 163; *In re Hawkins*, 486 F. 2d 577, 179 USPQ 167.

¶ 6.19.1 *Improper Incorporation by Reference*

The attempt to incorporate subject matter into this application by reference to [1] is improper because [2]

**Examiner Note:**

1. In bracket 1, identify the document such as a serial or patent number or other identification.
2. In bracket 2, give the reason why it is improper.<

The amendment must be accompanied by an affidavit or declaration executed by the applicant, or his >or her< attorney or agent, stating that the amendatory material consists of the *same* material incorporated by reference in the referencing application. *In re Hawkins*, 486 F. 2d 569, 179 USPQ 157; *In re Hawkins*, 486 F. 2d 579, 179 USPQ 163; *In re Hawkins*, 486 F. 2d 577, 179 USPQ 167, (CCPA, 1973).

Reliance upon a commonly assigned copending application by a different inventor may ordinarily be made for the purpose of completing the disclosure. See *In re Fried et al.*, 141 USPQ 27, 51-CCPA 1118 (1964), and *General Electric Company v. Brenner*, 407 F. 2d 1258, 159 USPQ 335 (CA DC 1968).

Since a disclosure must be complete as of the filing date,

subsequent publications or subsequently filed applications cannot be relied upon to establish a constructive reduction to practice.

C. DEPOSIT OF MICROORGANISMS  
>OR OTHER BIOLOGICAL MATERIAL<

Some inventions which are the subject of patent applications depend on the use of microorganisms >or other biological material< which must be described in the specification in accordance with 35 U.S.C. 112. No problem exists when the microorganisms >or other biological material< used are known and readily available to the public. When the invention depends on the use of a microorganism >or other biological material< which is not so known and readily available, applicants must take additional steps to comply with the requirements of >35 U.S.C.<\* 112.

*In re Argoudelis, et al.*, 168 USPQ 99 (CCPA, 1970), accepted a procedure for meeting the requirements of 35 U.S.C. 112. Accordingly, the Patent and Trademark Office will accept the following as complying with the requirements of >35 U.S.C.<\* 112 for an adequate disclosure of the microorganism >or other biological material< required to carry out the invention:

(1) the applicant no later than the effective filing date of the application has made a deposit of a culture of the microorganism >or other biological material< in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted, under conditions which assure (a) that access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and (b) that all restrictions on the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent;

(2) such deposit is referred to in the body of the specification as filed and is identified by deposit number, name and address of the depository, and the taxonomic description to the extent available is included in the specification; and

(3) the applicant or his assigns has provided assurance of permanent availability of the culture to the public through a depository meeting the requirements of (1). Such assurance may be in the form of an averment under oath or by declaration by the applicant to this effect.

>The Patent and Trademark Office will also accept the deposit of a suitable microorganism or other biological material made after the effective U.S. filing date of the application so long as the microorganism or other biological material is identified in the application as filed and a suitable deposit is made before the patent is granted, *In re Lundak*, 227 USPQ 90 (Fed. Cir. 1985). Unless applicants provide appropriate written assurances that a suitable deposit will be made in circumstances where it is considered to be necessary by the examiner, the examiner will make and maintain an appropriate rejection until a deposit is made, appropriate written assurances are provided, or it is determined that no deposit is required. Where appropriate written assurances are given, but no deposit has been made,

## PARTS, FORM AND CONTENT OF APPLICATION

608.01(q)

the examiner will make a requirement that a suitable deposit be made at the time of mailing the Notice of Allowance and Issue Fee Due, setting a time period for making the deposit. As noted in *Lundack*, an appropriate amendment to a pending application to identify the depository affording permanence to the deposit and the accession number for the deposit would not constitute new matter.

The requirement that applicants or their assigns provide assurances of permanent availability of the deposit is satisfied if the depository is contractually obligated to store the deposit for a reasonable time after expiration of the enforceable life of the patent. The Office will not insist on any particular period after expiration of the enforceable life of the patent. The enforceable life of the patent for this purpose is considered to be the original term of seventeen years plus six (6) years to cover the statute of limitations. Any deposit which is made under the Budapest Treaty will be for a term acceptable to the Office, unless the thirty years from the date of deposit will expire before the end of the enforceable life of the patent. With this one exception, any deposit made under the Budapest Treaty will meet all of the requirements for a suitable deposit except that assurances must also be provided that all restrictions on the availability to the public of the deposited microorganism or other biological material will be irrevocably removed upon the granting of the patent.

A copy of the applicant's contract with the depository may be required by the examiner to be made of record as evidence of making the culture available under the conditions stated above.

#### D. SIMULATED OR PREDICTED TEST RESULTS OR PROPHETIC EXAMPLES

Simulated or predicted test results and prophetic examples (paper examples) are permitted in patent applications. Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted. Paper examples should not be represented as work actually done. No results should be represented as actual results unless they have actually been achieved. Paper examples should not be described using the past tense.

NOTE. — For problems arising from the designation of materials by trademarks and trade names, see >MPEP< § 608.01(v).

#### 608.01(q) Substitute or Rewritten Specification [R-8]

##### 37 CFR 1.125 Substitute specification.

If the number or nature of the amendments shall render it difficult to consider the case, or to arrange the papers for printing or copying, the examiner may require the entire specification, including the claims, or any part thereof, to be rewritten. A substitute specification may not be accepted unless it has been required by the examiner or unless it is clear to the examiner that acceptance of a substitute specification would facilitate processing of the application. Any substitute specification

filed must be accompanied by a statement that the substitute specification includes no new matter. Such statement must be a verified statement if made by a person not registered to practice before the Office.

The specification is sometimes in such faulty English that a new specification is necessary; in such instances a new specification should be required.

Form Paragraph 6.28 may be used >where the specification is in faulty English<\*\*.

##### ¶ 6.28 Idiomatic English

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52 (a and b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter. Such statement must be a verified statement if made by a person not registered to practice before the Office.

>Form Paragraph 6.28.1 may be used to require a substitute specification for reasons other than faulty English.

##### ¶ 6.28.1 Substitute Specification

A substitute specification is required because [1]. The substitute specification filed must be accompanied by a statement that it contains no new matter. Such statement must be a verified statement if made by a person not registered to practice before the Office.

##### Examiner Note:

1. In bracket 1, insert clear and concise examples of why a new specification is required.
2. A new specification is required if the number or nature of the amendments render it difficult to consider the case or to arrange the papers for printing or copying. 37 CFR 1.125.
3. See also form paragraph 13.01 for partial rewritten specification.

Under current practice, substitute specifications may be voluntarily filed by the applicant if \*\*> desired<. A substitute specification will normally be accepted by the Office even if it has not been required by the examiner. Substitute specifications will be accepted if applicant submits therewith a \*\* marked-up copy \*> which shows< the portions of the original specification which are being added and deleted and a statement that the substitute specification includes no new matter and that the substitute specification includes the same changes as are indicated in the \*\*>marked-up copy of the< original specification >showing additions and deletions<. Such statement must be a verified statement if made by a person not registered to practice before the Office. Additions should be indicated by underlining and deletions should be indicated between brackets. Examiners may also require a substitute specification where it is considered to be necessary.

However, any substitute page of the specification, or entire specification, filed must be accompanied by \*\*>a statement< indicating that no new matter was included. >The statement must be verified if made by a person not registered to practice before the Office.< There is no obligation on the examiner to make a detailed comparison between the old and the new speci-